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BNFL Inc. Suggested Rewording

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Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis

April 15, 1999

Office of Radiological, Nuclear and Process
Safety Regulation for TWRS Privatization Contractors

Richland Operations Office
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Approved: _____

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PREFACE

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The Department of Energy's (DOE) Richland Operations Office (RL) issued a request for proposal in February 1996 for privatized processing of waste as part of the Hanford Tank Waste Remediation System (TWRS). Offerors were requested to submit proposals for the initial processing of the tank waste at the Hanford Site. Some of this radioactive waste has been stored in large underground storage tanks at the Site since 1944. Currently, approximately 54 million gallons of waste containing approximately 250,000 metric tons of processed chemicals and 215 million curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE intends to purchase waste processing services from a contractor-owned, contractor-operated facility through a fixed-price contract. DOE will provide the waste feedstock to be processed but maintain ownership of the waste. The contractor must: a) provide private financing; b) design the equipment and facility; c) apply for and receive required permits and licenses; d) construct the facility and commission its operation; e) operate the facility to process tank waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization Program is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort the objectives of which are to a) demonstrate the technical and business viability of using privatized contractors to process Hanford tank waste; b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; c) maintain environmental protection and compliance; and d) substantially reduce life-cycle costs and time required to process the tank waste. The Phase I effort consists of three parts: Part A, Part B-1, and Part B-2.

Part A is a twenty-month period to establish technical, operational, regulatory, and financial elements necessary for privatized waste processing services at fixed-unit prices. This includes identification by the TWRS Privatization Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months is for the Contractors to develop the Part-A deliverables and four months is for DOE to evaluate the deliverables and determine whether to authorize Contractors to perform Part B. Part A culminated in DOE's authorization on August 24, 1998, of BNFL Inc. to perform Part B.

Part B-1 is a twenty-four month period to a) further the waste processing system design introduced in Part A, b) revise the technical, operational, regulatory, and financial elements established in Part A, c) provide firm fixed-unit prices for the waste processing services, and d) achieve financial closure.

Part B-2 is a sixteen year period to complete design, construction, and permitting of the privatized facilities; provide waste processing services for representative tank wastes at firm fixed-unit prices; and deactivate the facilities. During Part B-2, approximately 10% of the total Hanford tank wastes will be processed.

Phase II will be a full-scale production effort. The objectives of Phase II are to implement the lessons learned from Phase I and to process all remaining tank waste into forms suitable for final disposal.

A key element of the TWRS Privatization Program is DOE's regulation of radiological, nuclear, and process safety through the establishment of a specifically defined regulatory approach and a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation is authorized by DOE through the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (referred to as the Policy) and is implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors* (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, RL; the Assistant Secretary for Environment, Safety and Health (EH-1); and the Assistant Secretary for Environmental Management (EM-1). The MOA is signed by the Manager, RL; the EH-1; and the EM-1. The MOA details certain interactions among RL, the EH-1, and the EM-1 as well as their respective roles and responsibilities for implementation of the regulatory approach.

The authority of the RU to regulate the TWRS Privatization Contractor is derived solely from the terms of the TWRS Privatization Contract. Its authority to regulate the Contractor on behalf of DOE is derived from the Policy. The characteristics and scope of this special regulatory approach (special in the sense that it is based on terms of a contract rather than formally promulgated regulations) are delineated in the MOA, the TWRS Privatization Contract, and the following four documents, which are incorporated into the Contract and are part of the MOA.

> *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005
>
> *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003
>
> *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006
>
> *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004

Regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractor from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

In the execution of the regulatory approach through its regulatory program, DOE expects the RU to consider not only the relevant approaches and practices of DOE but also those of the Nuclear Regulatory Commission (NRC). The Policy states that

> "It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU interacts with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation of TWRS-P Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities Campus, 100 Sprout Road, Richland, Washington for a nominal fee.

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REGULATORY UNIT POSITION ON CONTRACTOR-INITIATED CHANGES TO THE AUTHORIZATION BASIS

1.0 INTRODUCTION

The U. S. Department of Energy (DOE), Richland Operations Office (RL), Office of Radiological, Nuclear, and Process Safety of the TWRS-P Contractor (Regulatory Unit [RU]) positions described in this document are not requirements. These positions describe methods acceptable to the RU for evaluating and implementing Contractor-initiated changes to the Authorization Basis. In particular, the Tank Waste Remediation System Privatization (TWRS-P) Contractor has the responsibility to establish an appropriate standard for evaluating and implementing Contractor-initiated changes in the Safety Requirements Document (SRD). The process for performing such changes is expected to be detailed in the Integrated Safety Management Plan (ISMP). Conformance with the positions described in this document does not alter the Contractor=s responsibility for ensuring that standards established or identified in the SRD will provide adequate safety, comply with all applicable laws and regulations, and conform to top-level safety standards.

The TWRS-P regulatory process involves multiple steps of Contractor submittals and specific regulatory actions. Contractor submittals provide the information and commitments that serve as the basis for regulatory decisions taken by the RU in connection with regulatory actions and establish the Authorization Basis. The existence of an Authorization Basis starts with Standards Approval, which is the first regulatory action.

The Authorization Basis is not just relevant to specific RU decisions but also serves several functions following the completion of a specific regulatory action. The Authorization Basis describes the safety basis for the facility and is the benchmark used to evaluate the safety implications of changes made to a Contractor=s facility design, operations, or administrative controls. The SRD portion of the Authorization Basis identifies the standards with which the Contractor will use to design, construct and operate the facility and with which RU will assess Contractor performance during each stage of the regulatory process. The importance of the Authorization Basis to these ongoing activities and the need to maintain a credible safety basis for the facility, requires that the Authorization Basis be maintained current.

As a fundamental precept underlying this position paper, the RU expects each Contractor to be responsible for performing work safely by meeting the provisions of adequate safety, complying with all applicable rules and regulations, and conforming to the top-level standards and principles. The RU action of Standards Approval includes both (1) the approval of the Contractor-recommended set of radiological, nuclear, and process safety standards and requirements, and (2) the approval of the Contractor=s integrated safety management processes ensuring safe performance of work. Contractor-initiated changes to both the standards and the integrated safety management program are addressed in this position paper.

The maturation of the Contractor's facility design and activities, and other changing conditions, result in a need to establish a process for the Contractor to make changes to the Authorization Basis. This process needs to balance the TWRS-P regulatory principle of efficiency with assurance that adequate safety will not be compromised. Furthermore, DOE=s policy is to regulate TWRS-P Contractor activities in a manner that assures adequate safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission (NRC). The RU recognizes that specific NRC procedures cannot be simply applied since those procedures are designed to operate within a specific set of NRC regulations and guidance that do not exist in the TWRS-P environment. The RU position regarding Contractor-initiated changes was developed to conform with these program requirements and with the applicable portions of DOE/RL-96-0006, *Top-level Radiological, Nuclear, And Process Safety Standards and Principles for TWRS Privatization Contractors*.

2.0 DEFINITIONS

Authorization Basis: The composite of information provided by a Contractor in response to radiological, nuclear, and process safety requirements that is the basis on which the Director of the Regulatory Unit grants permission to perform regulated activities.[1] The Authorization Basis includes that information requested by the Contractor for inclusion in the Authorization Basis and subsequently accepted by the RU.[2] Examples of such information include:[3]

1. The information submitted in connection with a request for Standards Approval, a request for Construction Authorization, a request for Operations Authorization, or an Initial Safety Analysis. This includes the information associated with the requests as described in DOE/RL-96-0003, *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors,* and any other information submitted by the Contractor in connection with the requests.[4]

2. Amendments to the information described above that are on the Contractor docket. Such amendments may be in the form of revisions to previously submitted documents, or new information that supplements previously submitted information.

An Authorization Basis begins at the Standards Approval regulatory action and continues throughout the design, construction, operation, and decommissioning of a TWRS-P Contractor facility.[5]

Unreviewed Safety Question (USQ): A safety question where any of the following conditions are satisfied: (1) the probability of occurrence or the radiological consequences of an accident or malfunction of equipment important to safety, previously evaluated in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility analysis, may be increased; (2) a possibility for an accident or equipment malfunction of a different type than any evaluated previously in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility safety analysis, may be created; or (3) any margin of safety is reduced.[6]

Margin of Safety: The level of confidence that is assigned to the integrity of radiological and nuclear control measures such as confinement barriers. It is defined as the range between the design acceptance limits and the design failure point of the control feature. The design acceptance limits for radiological control measures such as confinement barriers are established during the design of the facility. These criteria are given in terms of those physical parameters that define their performance. Whenever the values of the design acceptance limits are exceeded, the margin of safety, and therefore the confidence in the integrity of the control feature, is decreased.

Technical Safety Requirement (TSR): Those requirements that define the conditions, the safe boundaries, and the management or administrative controls necessary to ensure the safe operation of the facility, reduce the potential risk to the public and facility workers from uncontrolled releases of radioactive materials, and from radiation exposures due to inadvertent criticality.[7] The TSRs are approved as part of the Production Operations Authorization regulatory action.

Safety Requirements Document (SRD): A document that contains the approved and mandated set of radiological, nuclear, and process safety standards and requirements which, if implemented, provides adequate protection of workers, the public, and the environment against the hazards associated with the operation of the Contractor=s facilities.[8] The SRD is approved as part of the Standards Approval regulatory action.

Changes: Changes to the facility design and administrative controls (e.g., procedures, programs, plans, or management processes) that are described in the Authorization Basis or relied upon by the Contractor to ensure conformance to the Authorization Basis.[9]

Quality Assurance Program (QAP): The Quality Assurance Program as required by 10 CFR 830.120, AQuality Assurance Requirements.@

Radiation Protection Program (RPP): The Radiation Protection Program as required by 10 CFR 835, AOccupational Radiation Protection.@

Top-Level Safety Standards: Any of the safety standards or principles established in DOE/RL-96-0006, *Top-level Radiological, Nuclear, And Process Safety Standards and Principles for TWRS Privatization Contractors*.

3.0 POSITION

3.1 The processes associated with evaluating and implementing changes are, themselves, important-to-safety. Accordingly, Contractor evaluation and implementation of changes shall be accomplished:

a. By qualified personnel

b. In accordance with procedures developed and approved under the Contractor's procedure process

c. Under the Contractor's approved Quality Assurance Program (QAP).

3.2 Contractors may make changes if a~~n evaluation~~ review is performed and either:[10]

a. The ~~evaluation~~ review demonstrates a proposed change is consistent with the existing Authorization Basis; or

b. The Authorization Basis is revised prior to implementation of the proposed change.

3.3 Revisions to the Authorization Basis that involve a change to the QAP shall be accomplished in accordance with the provisions of 10 CFR 830.120.

3.4 Revisions to the Authorization Basis that involve a change to the RPP shall be accomplished in accordance with the provisions of 10 CFR 835.

3.5 Revisions to the Authorization Basis, other than to the QAP or RPP,[11] may be made by the Contractor without prior Regulatory Unit (RU) approval, provided that:

a. A safety evaluation is performed which demonstrates that the revision:

(1) Does not involve the deletion or modification of a standard previously identified or established in the approved SRD[12]

(2) Does not involve the modification of an approved Technical Safety Requirement (TSR)[13]

(3) Does not result in a reduction in commitment currently described in the Authorization Basis[14]

(4) Does not result in a reduction in the effectiveness of any program, procedure, or plan described in the Authorization Basis[15]

(5) Does not result in an Unreviewed Safety Question (USQ), if a Production Operations Authorization has been issued.[16]

b. The following documentation requirements are met:

- All changes, Authorization Basis revisions, and associated safety evaluations performed in conformance with Position 3.5.a shall be documented.

- Documentation shall be retained and readily available for RU review.[17]

- Safety ~~Evaluations~~ evaluations should be documented in sufficient detail such that a knowledgeable individual reviewing the evaluation can identify the technical issues considered during the evaluation and basis for the determinations.

- The RU shall be notified of revisions to the Authorization Basis within 30-days of completing such revisions.

3.6 An Authorization Basis revision not meeting the conditions of Position 3.5 may be implemented following approval by the Regulatory Official of a request to amend the Authorization Basis. An amendment request shall include:

a. A description of the proposed revision

b. A reason for the proposed revision

c. A description of the proposed implementation schedule for the revision and associated change(s)

d. A copy of the Authorization Basis document or appropriate excerpt showing the proposed revision

e. An evaluation of the proposed revision as described in 3.5.a

f. If the revision involves the deletion or modification of a standard previously identified in the approved SRD:[18]

(1) an evaluation that demonstrates the revised SRD will continue to identify a set of standards that will provide adequate safety, comply with all applicable laws and regulations, and conform to top-level safety standards; and

(2) certification that the revised SRD will identify a set of standards that will continue to provide adequate safety, comply with all applicable laws and regulations, and conform to top-level safety standards.

3.7 Notwithstanding the provisions of Positions 3.2, 3.5 and 3.6, during the design and construction phases, the Contractor may, at its own risk, implement a change prior to revision of the Authorization Basis if:

a. Cold Testing of the facility has not yet commenced,

b. the Contractor has assessed the change against the following guidelines to determine if it is appropriate to implement the change at risk:

Proceed at risk will not be used for changes that meet any of the following:

1. Design changes that would not meet SRD Safety Criteria or top-level safety standards

2. Changes to Implementing Standards that would have broad design implications

3. Design changes that would result in significant dose increases to workers or the public

4. Design changes that would result in introduction of significant new hazards.

Proceed at risk may be used for changes that meet the following:

1. Changes whose delay pending AB revision would result in significant cost or schedule impact, and

2. Design changes that are physically reversible at an acceptable cost, as determined by the appropriate Design Manager or Area Project Manager, and any of the following:

   a) Changes involving interpretations to or tailoring of Implementing Standards that would have limited design implications and are judged to have no significant safety impact.

   b) Design changes that may increase the consequences of a previously-evaluated design basis event (DBE), but not significantly (i.e., the consequences are judged to be well below the applicable exposure standards).

   c) Design changes that would result in a new DBE, but the consequences are judged to be well below the applicable exposure standards.

   d) Changes where prior Regulatory Unit approval is not required.

c. the Contractor has informed the Regulatory Official (or his designee) of the change, if Regulatory Unit approval is required,

d. the Contractor has established and implemented controls to identify and track the change pending revision of the Authorization Basis, and

e. the Contractor undoes implementation of the change in the event that the Regulatory Unit rejects the requested revision of the Authorization Basis (if approval was required).

4.0 NOTES

1. Definition taken from DOE/RL-96-0006, *Top-level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*.

2. Statement was added to clarify that information is included in the Authorization Basis based on a specific proposal by the Contractor and subsequent acceptance by the RU.

3. This information was included to provide specific examples of information included in the Authorization Basis.

4. Documents submitted to the RU in connection with a regulatory action may be superceded by documents submitted in subsequent regulatory actions. For example, the Preliminary Safety Analysis Report submitted in a Construction Authorization request may be superceded by a Final Safety Analysis Report submitted in an Operations Authorization request. A Contractor may request that information and commitments made in superceded documents be removed from the Authorization Basis.

5. Statement was included to make it clear when the Authorization Basis is considered to come into existence and, therefore, needs to be considered when making changes.

6. Definition taken from DOE/RL-96-0006, *Top-level Radiological, Nuclear, And Process Safety Standards and Principles for TWRS Privatization Contractors*. For the purpose of this document, the phrase or other related safety analysis and evaluations not yet included in the updated facility analysis is intended to clarify that the Contractor is expected to perform evaluations related to USQ determinations using the latest current safety analysis as maintained by the Contractor, not the safety analysis previously described in the last submittal of an updated safety analysis report.

7. Definition taken from DOE/RL-96-0006, *Top-level Radiological, Nuclear, And Process Safety Standards and Principles for TWRS Privatization Contractors*.

8. Definition taken from DOE/RL-96-0006, *Top-level Radiological, Nuclear, And Process Safety Standards and Principles for TWRS Privatization Contractors*.

9. The term “Changes” was defined to simplify the references to them throughout the balance of this paper since the contract uses unrelated language to refer to the administrative features of the facility. Included within the scope of “changes” are those items that may not be explicitly described in the Authorization Basis, but where changes would cause a deviation from commitments contained in the Authorization Basis.

10. This step is based on the assumption that it is possible for any Change to potentially affect the

Authorization Basis. This position should not be used to preclude the contractor from establishing a class of SSCs and/or administrative features for which changes do not have the possibility of affecting the Authorization Basis and, therefore, would not require such an evaluation.

11. The QAP and RPP are excluded from the 3.5.a evaluation process since the applicable CFRs establish the process for changes to these documents (see 3.3 and 3.4).

12. The TWRS-P SRD does not really have a direct parallel in the NRC or existing DOE regulatory environments. In simple terms, the SRD establishes the set of requirements that are: (1) to be complied with by the Contractor, **and** (2) provide the basis for regulatory oversight and assessment. The SRD does not simply identify information and commitments presented by the Contractor in order to demonstrate conformance with requirements (a more typical case for a Alicense basis@ or Aauthorization basis@ document). The SRD is derived from a significantly different basis and process than other aspects of the Authorization Basis. For these reasons, the SRD is excluded from the change mechanism provided under 3.5.a.

The Standards Approval regulatory action results in RU approval of a set of standards that, if properly implemented, will ensure adequate safety. Standards added to the SRD following Standards Approval must be consistent with the set of standards identified in the approved SRD or the Contractor must request RU approval of a change to the approved standards set. Accordingly, additions to the SRD should not require prior RU approval unless a modification to the existing approved standards set is necessary. As provided for in Position 3.5.b, the RU will conduct oversight of additions to the SRD standards set during the design and construction phases of the Contractor facilities. Ultimately, all changes to the SRD, including additions to the approved SRD standards set, will be reviewed and dispositioned by the RU as part of the Construction Authorization and Production Operations Authorization actions of the regulatory process.

13. The TSRs are excluded from the 3.5.a evaluation/change process based on consistency with NRC and DOE treatment of similar items.

14. This evaluation criterion was established as one of two tests to be applied before implementation of a USQ determination. The reduction in commitment and reduction in effectiveness standards have history in the NRC and DOE regulatory environments with regard to screening changes.

15. This criterion was established as one of two tests to be applied before implementation of a USQ determination. The reduction in commitment and reduction in effectiveness standards have history in the NRC and DOE regulatory environments with regard to screening changes.

16. The evaluation criterion associated with the USQ is the typical standard used in the NRC and DOE environments for screening changes after a license/agreement has been issued based on an

FSAR. Prior to an FSAR, there are no established consequences, margins, or set of accidents and malfunctions that can be used as a basis for a USQ determination during an evaluation. Accordingly, the USQ test is not applied prior to the Contractor prior to having an operations agreement. In order to ensure conformance to a specific safety standard in activities prior to operations, the RU must ensure that the SRD establishes appropriate standards.

17. It is expected that the RU will periodically audit Change documentation and evaluations to determine compliance and to fine-tune the Contractor interpretation of when the RU should become involved in the Change process.

18. This position requires, for changes to committed standards in the SRD, that the Contractor specifically evaluate conformance with the "Safety Triad" (i.e., the contractual regulatory principle which requires that the contractor's set of standards in the SRD will; (1) achieve adequate safety, (2) comply with applicable laws and legal requirements, and (3) conform with top-level safety standards and principles) and provide certification that the concepts of the "Safety Triad" are still being addressed. This is to maintain fidelity with original process for developing the SRD when making changes.